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Michigan Based Pharmaceutical Wholesaler Harvard Drug Group To Pay U.S. \$8,000,000 In Settlement



Drug Enforcement Administration

Detroit

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FOR IMMEDIATE RELEASE

Michigan Based Pharmaceutical Wholesaler Harvard Drug Group To Pay U.S. \$8,000,000 In Settlement

Harvard alleged to have violated Controlled Substances Act

United States Attorney Barbara McQuade and U.S. Drug Enforcement (DEA) Special Agent in Charge Robert L. Corso announced today a settlement between the government and Harvard Drug Group, LLC, which resolves allegations that Harvard violated the Controlled Substances (CSA). Harvard is alleged to have violated the CSA by failing to have in place an effective system designed to identify suspicious orders of controlled substances, and to report suspicious orders of those substances to the DEA. The settlement calls for the payment of \$8,000,000 to the government over the next three years, and the government has agreed to suspend payment of the final \$2,000,000 of this amount if Harvard demonstrates that it has implemented an effective regulatory compliance program.

The CSA requires distributors of pharmaceuticals, such as Harvard, to have in place systems that reliably identify suspicious orders - for example, those of unusual size, those that are unusually frequent, or those that substantially deviate from a normal pattern - of controlled substances. In this case, a DEA investigation revealed that between March, 2009 and May, 2010, Harvard had received over 1,000 suspicious orders for Schedule II narcotics - primarily oxycodone - that should have triggered further investigation by the company and reporting to the DEA. Many of the suspicious orders involved a repeated pattern, wherein the ordering entity made a single order look like multiple smaller orders.

Contemporaneously with this settlement, Harvard is resolving an administrative complaint with the DEA. The case was investigated by DEA Detroit's Office of Diversion Control.



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